UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

CHAMBERS OF
PAUL W. GRIMM
UNITED STATES DISTRICT JUDGE

6500 CHERRYWOOD LANE
GREENBELT, MARYLAND 20770
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April 15, 2022

RE: *American Academy of Pediatrics, et al. v. FDA*,
PWG-18-883

LETTER ORDER

Dear Counsel:

This letter order addresses Plaintiffs' letter, construed as a motion, seeking a modification to the remedial order issued in this case, specifically to require the FDA to provide regular status reports, ECF No. 195. I have reviewed the filings[1] and the proposed language, and do not find a hearing necessary. *See* Loc. R. 105.6 (D. Md. 2021). For the following reasons, I shall grant Plaintiffs' motion, and a revised remedial order shall be issued separately.

In May 2019, I vacated FDA's August 2017 Guidance for violating the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.*, and subsequently issued a remedial order that imposed a deadline by which the FDA would review new e-cigarette product applications so the products could not remain on the market unreviewed. ECF Nos. 73, 74, 127. The order was later clarified, ECF No. 132, and modified to extend the premarket application deadline in light of the COVID-19 pandemic, ECF No. 182. Plaintiffs now seek to modify the order pursuant to Federal Rule of Civil Procedure 60(b)(5) to add a requirement for regular FDA reports. Mot. 2. FDA does not believe status reports are warranted at this time. Resp. 1.

The Court has discretion to modify a final order when "applying it prospectively is no longer equitable," Fed. R. Civ. P. 60(b)(5), or for "any other reason that justifies relief," *id.* at (b)(6). *See Hensley v. Chesapeake & O. Ry. Co.*, 651 F.2d 226, 229 (4th Cir. 1981) (noting a trial court's discretion on a Rule 60(b) motion). The party seeking modification bears the burden of showing that there has been "a significant change either in factual conditions or in the law." *Horne v. Flores*, 557 U.S. 433, 447 (2009). Although I determined when I issued the remedial order that there was not a "present need to require court monitoring through quarterly reports," I retained jurisdiction to ensure that further action could be taken if circumstances changed. ECF No. 127 at 12.

Plaintiffs have satisfied their burden of showing significant factual changes that support modifying the remedial order at this time, and the FDA has not disputed Plaintiffs' assertions.

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[1] Plaintiff's letter motion, ECF No. 195; FDA's letter response, ECF No. 197; and Plaintiffs' letter reply, ECF No. 200, with the proposed amendment language, ECF No. 200-1.

Plaintiffs report that the "e-cigarette products with the greatest public health impact – both overall and among kids – remain on the market for an indeterminate amount of time, despite receiving no FDA authorization." Mot. 3. The FDA reports that it has completed millions of phased product reviews in about 98% of the timely premarket applications and continues to devote significant resources to resolve the remaining pending applications while also defending challenges to its application denials and initiating regulatory efforts against products without premarket authorization. Resp. 2-3. However, the popular products used by young people remain on the market unreviewed,[2] which is inconsistent with the purpose of this Court's judgment. Plaintiffs' proposed reporting requirement will inform the Court and public when the FDA expects to take action on those products that account for the largest share of the market. The reporting is tailored to allow the Court to assess the FDA's progress, or lack thereof, towards achieving the goals of the remedial order. Accordingly, I shall grant Plaintiffs' motion to modify the order to add a limited reporting requirement.

Plaintiffs and the FDA have conferred and agreed on the wording of paragraphs 6 and 7 of the proposed amended order. Reply 3; Prop. Order 1, ECF No. 200-1. Therefore, I shall implement those changes pursuant to the parties' agreement. A third proposed paragraph remains disputed, and I have determined that the most appropriate wording is found under the FDA's proposed "Option B." *See* Prop. Order 2. The Option B language adopts the Plaintiffs' definition of "Covered Applications,"[3] requires the FDA to forecast the percentages of such products for which it expects to have taken "action" by June 2022 and quarterly thereafter, using a definition of action that includes the regulatory responses of most concern to Plaintiffs— the issuance of a marketing order, refuse-to-accept letter, refuse-to-file letter, or marketing denial order. I find that the additional detailed reporting sought by Plaintiffs in their proposed "Option A" is too burdensome to impose on FDA at this time.

Although informal, this is an Order of the Court and shall be docketed as such. A Revised Remedial Order shall be issued separately.

Sincerely,

/S/
Paul W. Grimm
United States District Judge

[2] "FDA does not appear to have enforced the premarket review requirements against *any* product still awaiting a [Premarket Tobacco Product Application] decision, including products with the greatest market share and those most used by youth." Mot. 3.

[3] Including the most popular e-cigarette brands that are most deleterious to youthful populations.